REMARKS/ARGUMENTS

Claims 3, 5-14, and 48-61 are pending.

Favorable reconsideration is respectfully requested in view of the reasons as set forth in the Amendment submitted October 27, 2008, the Third Declaration under 37 CFR 1.132 of Dr. Charli Kruse submitted herewith, and the following remarks.

Rejection under 35 USC § 112, first paragraph

Claims 3, 5-14, and 48-61 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. This rejection is respectfully traversed for the reasons as set forth in the Amendment submitted October 27, 2008, and as further set forth below.

The Examiner argues that the total lack of enablement is raised based on the lack of evidence in the specification that the claimed cells express surface antigens that characterize pluripotent cells, and that the claimed cells have a normal karyotype. The Examiner has cited the NIH document which lists its criteria for ES cells (Office Action at page 3). The Examiner argues that while the instant specification teaches that the pancreatic stem cells can differentiate into nerve cells (expressing PGP 9.5. and NF), glial cells (expressing S100 and GFAP), muscle cells (expressing SMA), cartilage (expressing collagen type II), exocrine glandular cells (expressing amylase and trypsin), endocrine glandular cells (expressing insulin) and epidermal cells (expressing cytokeratin), following organoid body formation, the Specification does not teach that the instant cells express cell surface markers associated with pluripotent cells and that they exhibit a normal karyotype (Office Action at page 4).

The test of enablement is whether one reasonably skilled in the art could make or use the

invention from the disclosures in the patent coupled with information known in the art without undue experimentation. United States v. Telectronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 USC 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. In re Marzocchi, 439 F.2d 220, 224 (CCPA 1971).

Here, the claims are enabled because there is not any reason to doubt the objective truth of the statements contained in the Specification for enabling support. The Specification discloses the manner and process for making and using the claimed invention, including working examples which show the efficacy of the claimed invention. For example, the Specification presents examples of pluripotent stem cells isolated from pancreas of human and rat, and that these cells have been shown to differentiate into nerve, glia, cartilage, exocrine and endocrine cells (see Specification at ¶[0061] to ¶[0062]. In addition, Dr. Kruse's previously submitted Rule 1.132 Declarations describe how experimental protocols described in the application were used to prepare isolated pluripotent adult stem (IPAS) cells from fourteen different species of animals.

The Examiner further argues that while the specification provides guidance for pluripotent stem cells from rat and human pancreas, the Examiner alleges that the 132 does not teach that pancreatic tissue from goat differentiates into the same cell types as that of rat and human (Office Action at pages 4-5).

However, submitted herewith is a Third Declaration of Dr. Kruse under 37 CFR 1.132 presenting experimental data. This experimental data includes evidence that pluripotent stem cells can be isolated from pancreatic tissue of a third species, i.e. goat. The characterization of the cells has been implemented and presented similar to the experiments involving cells from salivary glands submitted previously in the prosecution of this application. The differentiated cells stained positive for several cell markers having specificity for different cells of all 3 germ layers. The differentiated cells stained positive for the ectodermal cell markers GFAP and neurofilaments (see Figure 1A and 1B). The differentiated cells stained positive for the mesodermal markers collagen-II and α-smooth muscle actin (see Figure 2A and 2B). The differentiated cells stained positive for the endodermal marker cytokeranin 18 and amylase (see Figure 3A and 3B)(see the Third Declaration of Dr. Kruse at ¶8).

With respect to the confirmation of a normal karyotype, Dr. Kruse submits the results obtained by an independent cytogenetic laboratory located in Kaiserslautern, Germany. The findings of the independent cytogenetic laboratory are set forth in the summarizing opinion (see Declaration of Dr. Kruse, ¶9, and Appendix A, "Beurteilung") with respect to the specimen (translated form the German):

> Numerically and structural inconspicuous female karyotype, the satellite extension at one chromosome 22 is a normal variation without pathologic relevance.

Therefore, according to the evidence presented in the Third Declaration of Dr. Kruse the pluripotent stem cells isolated from pancreas maintain a normal karyotype.

With regard to the issue of whether the presence of nestin is indicative for a neuronal

stem cell, Applicant has submitted the Kajahn reference (Kajahn, J., et al., Skin-derived human adult stem cells surprisingly share many features with human pancreatic stem cells. Eur. J. Cell Biol. (2007)) which demonstrates that the marker nestin as an indicator of pluripotency has been demonstrated for pancreatic stem cells and skin-derived cells in Figs. 1 and 2 of Kajahn et al.

Here, the Specification presents examples of pluripotent stem cells isolated from pancreas of human and rat, and that these cells have been shown to differentiate into nerve, glia, cartilage, exocrine and endocrine cells. Evidence has been submitted in the form of 1.132 Declarations showing isolation of stem cells from goat, and well as other mammals, and that the cells maintain a normal karyotype. The Specification teaches that the pancreatic stem cells can differentiate into nerve cells, glial cells, muscle cells, cartilage, exocrine glandular cells, endocrine glandular cells and epidermal cells.

Accordingly, reconsideration and withdrawal of the rejection of claims 3, 5-14, and 48-61 under 35 U.S.C. 112, first paragraph is respectfully requested.

* * *

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
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Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.